HIV+HEP
POLICY INSTITUTE

December 21, 2020

Commissioner Michael Conway
Chair, Regulatory Framework (B) Task Force
National Association of Insurance Commissioners
444 North Capitol Street NW
Suite 700
Washington, DC 20001

Re: Comments on NAIC Draft Pharmacy Benefit Manager Model Law

Dear Commissioner Conway and Task Force Members:

The **HIV+HEP Policy Institute,** a leading HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions, is pleased to submit comments on the draft NAIC Pharmacy Benefits Manager (PBM) Model Law. Access and affordability to lifesaving medications for people with HIV, hepatitis, and so many other illnesses are mainly controlled by unregulated PBMs. We are pleased that the NAIC has turned its attention to the important role PBMs play in the prescription drug market. We submitted comments and redline edits on the original draft and participated in all the meetings of the PBM Regulatory Issues (B) Subgroup.

While the Subgroup has proposed a minimal draft Model Law for the NAIC to consider that establishes a licensing and registration process for PBMs, we are disappointed that it does not fully provide states with the tools needed to properly regulate PBMs to protect patients nor does it consider the Subgroup's charge to consider "PBM prescription drug pricing and cost transparency."

Instead of providing specific model law language for states to consider on most of the issues, the Subgroup chose to include a lengthy drafting note that provides examples of laws passed by states that address many of the important issues involving PBMs. Areas in which we believe the Subgroup should have proposed specific language pertain to 1) ensuring greater transparency in the work of PBMs, 2) ensuring greater enforcement, 3) establishing that PBMs have a fiduciary relationship with health carriers, and 4) allowing PBMs to pass rebates on to consumers.

While some of these topics were addressed in the drafting note for Section 8, the issue of fiduciary relationship with health carriers was completely ignored as a potential item for

inclusion. **Therefore, HIV+Hep suggests that "Business Practices" be added to the list of items that states may want to consider and include as an example the Nebraska state law NV Rev. Stat. 683A.178 that establishes a "pharmacy benefit manager has a fiduciary duty to a third party with which the pharmacy benefit manager has entered into a contract to manage the pharmacy benefits plan of the third party."**

The recent unanimous ruling by the Supreme Court in *Rutledge vs. Pharmaceutical Care Management Association (PCMA)*, which concluded that the Employee Retirement Income Security Act of 1974 (ERISA) did not preempt an Arkansas state PBM law, will pave the way for more meaningful state regulation of PBMs. This provides more reason for the NAIC to adopt a stronger and clearer model act.

In addition to the above suggestion to include reference to the Nebraska statute, **HIV+Hep** suggests that the additional state laws be included in the Section 8 drafting note:

- **(4) Rebates:**
    - **Georgia O.C.G.A. § 33-64-10**. (b) A pharmacy benefits manager shall offer a health plan the ability to receive 100 percent of all rebates it receives from pharmaceutical manufacturers. In addition, a pharmacy benefits manager shall report annually to each health plan and the department the aggregate amount of all rebates and other payments that the pharmacy benefits manager received from pharmaceutical manufacturers in connection with claims if administered on behalf of the health plan.
    - **Maine Title 24-A: MAINE INSURANCE CODE. Chapter 56-C: HEALTH PLANS THAT PROVIDE PRESCRIPTION DRUG BENEFITS.** 1. Compensation used to reduce point-of-sale costs, improve benefits or lower premiums. All compensation remitted by or on behalf of a pharmaceutical manufacturer, developer or labeler, directly or indirectly, to a carrier, or to a pharmacy benefits manager under contract with a carrier, related to its prescription drug benefits must be: A. Remitted directly to the covered person at the point of sale to reduce the out-of-pocket cost to the covered person associated with a particular prescription drug; or B. Remitted to, and retained by, the carrier. Compensation remitted to the carrier must be applied by the carrier in its plan design and in future plan years to offset the premium for covered persons.
- **(5) Prohibitions and limitations on the corporate practice of medicine**
    - **Georgia O.C.G.A. § 33-64-4.** Pharmacy benefits manager shall not engage in the practice of medicine; recommended use of licensed physician.
- (**15) Transparency provisions**
    - **Washington State RCW 43.71C.030. Pharmacy benefit managers—Data reporting. https://app.leg.wa.gov/RCW/default.aspx?cite=43.71C.030**.

Even without a comprehensive NAIC model act, states are acting on their own and passing meaningful PBM laws. According to the National Academy of State Health Policy (NASHP), since 2017, 46 states have implemented more than 90 laws regulating PBMs. With the *Rutledge* decision, more will soon follow.

While state insurance commissioners have long regulated insurers, most formulary decisions, prior authorizations, and tiering are determined by PBMs. Unfortunately, these decisions are not always based on sound medicine but highly influenced by the amount of rebates PBMs receive from drug manufacturers. This, in turn, translates into how much beneficiaries pay for their prescription drugs.

Rebates and other price concessions negotiated by the PBMs with drug manufacturers play a significant role in determining not only formularies and tiering but also prior authorization, step-therapy, and other utilization management techniques. These additional access restrictions present substantial barriers for people trying to access their medications prescribed by their providers to best meet patients' medical needs. PBMs also decide whether new and innovative medications are added to formularies and dictate the removal of approved medications from formularies, often done midyear, which force patients to switch from medically stable treatments.

While there has been great public attention to the problem of high drug prices, PBMs play an increasingly significant role in why we in the United States have high drug prices. They demand substantial rebates from manufacturers and negotiate fees from health insurers. A recent analysis of 2018 spending by the Berkeley Research Group found that health insurers, hospitals, pharmacies, and other health system payers received nearly 50 percent of what was spent on brand medicines in 2018, up from 33 percent five years ago.[1] While some of these rebates are statutorily mandated, the increase has been largely driven by higher rebates negotiated by PBMs. However, these rebates are very rarely passed onto consumers. Instead, they incentivize manufacturers to set high list prices in order to account for the rebates that are expected by purchasers and actors in the drug supply chain.

Drug Channels Institute estimated for 2019 that the gross-to-net bubble—the dollar gap between sales at brand-name drugs' list prices and their sales at net prices after rebates and other reductions—reached $175 billion. This is an increase from $166 billion in 2018 and an increase of $73 billion from just five years ago.[2] PBMs have an important role in creating the gap between list and sales price.

To complicate matters, much of this is being done without any regulation and transparency. Laws aimed to ensure proper licensing and business practices of PBMs are critically important and many states have taken steps to do just that. After a reporting requirement law was passed in Texas, a recent study found that while PBMs received almost $857.5 million from pharmaceutical drug manufacturers, only $16 million was passed on to enrollees, while $177.6

[1] BRG, "Revising the Pharmaceutical Supply Chain: 2013 – 2018," January 9, 2020, https://www.thinkbrg.com/insights/publications/revisiting-the-pharmaceutical-supply-chain-2013-2018/.
[2] Drug Channels Institute, "The Gross-to-net Bubble Hit $175 Billion in 2019: Why Patients Need Rebate Reform," August 4, 2020, https://www.drugchannels.net/2020/08/the-gross-to-net-bubble-hit-175-billion.html.

million was retained by the PBMs as revenue and $663.9 million was passed onto the health issuers.[3]

For all of these reasons, the HIV+Hep Policy Institute strongly supports the NAIC in taking steps to improve state insurance department regulation of PBMs "to promote, preserve and protect the public health, safety and welfare."

Clearly, it is long past time for state insurance commissioners to regulate PBMs. On behalf of patients across the country who are struggling to access and afford their prescription medications, we thank you for undertaking this process to draft a model PBM law and appreciate the opportunity to provide comments on the draft. We look forward to future deliberations as the NAIC moves forward with this important work.

Should you have any questions or comments, please feel free to contact me at cschmid@hivhep.org or (202) 462-3042. Thank you.

Sincerely,

Carl E. Schmid II
Executive Director

cc: Jolie Matthews

[3] "Prescription Drug Cost Transparency, Pharmacy Benefit Managers," https://www.tdi.texas.gov/reports/documents/drug-price-transparency-PBMs.pdf.